

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' REPLY TO RESPONSE OF KLINE & SPECTER PLAINTIFFS TO
DEFENDANTS' MOTION FOR ORDER REGARDING DISPOSITION
OF NON-REVISION GYNECARE TVT PRODUCTS CASES¹**

The Kline & Specter Plaintiffs ("K&S Plaintiffs") are largely in agreement with the Order proposed by Ethicon but have requested three modifications. *See* Kline & Specter Plaintiffs' Memorandum in Response to Defendants' Motion for Order Regarding Disposition of Non-Revision Gynecare TVT Products Cases [Doc. No. 5431]; *see also* Proposed Order, Exhibit A to Defendants' Motion [Doc. No. 5313].

As a whole, these proposed changes would greatly decrease the number of plaintiffs who can participate in the election procedure, would increase the number of patients who can re-file lawsuits in the future, and would delay the finality of this litigation. The objections of relatively few plaintiffs out of the thousands of plaintiffs to which the Proposed Order is applicable should not de-rail the process for everyone. This is particularly true when any plaintiff has the option to decline to participate and to continue with her case.

First, K&S Plaintiffs want to include as a "Revision Surgery" minor, in-office procedures where local anesthesia is used, thus 1) reducing the number of plaintiffs who are "non-revised"

¹ In their response, the K&S Plaintiffs also dispute whether certain Plaintiffs belong on Exhibit A to Defendants' Motion. Defendants will respond to this contention in a separate filing.

and eligible to participate in the election procedure, and 2) increasing the number of cases that could be re-filed. As explained below, these procedures are very minor, are well-known risks of any mesh device, and do not reach the level of the more serious injuries which are already accounted for in Defendants' proposed order.

Second, the K&S Plaintiffs also want to include any future surgery funded by a plaintiff lawyer or a litigation funding company as a qualifying revision. This proposed change incentivizes unlawful and unethical behavior, and the K&S Plaintiffs have offered no valid reason for these changes.

The third suggested change, which requests Defendants to submit a Defense Fact Sheet in cases where a plaintiff elects not to dismiss her claim, is not disputed here, except that Ethicon requests 60 days to provide the Defense Fact Sheet, instead of the 30 days proposed by the K&S Plaintiffs.

A. Including minor, in-office procedures using local anesthetic within the definition of "Revision Surgery" will exclude many plaintiffs from participating in the election procedure, will increase the number of claims that can be re-filed, and will delay finality of this litigation.

The K&S Plaintiffs have suggested that in-office procedures using a local anesthetic be included as a qualifying Revision Surgery. *See* Pls.' Mem. [Doc. No. 5431] at 2. This change expands the definition of Revision Surgery and will vastly increase the number of plaintiffs in this litigation that will be deemed to have been "revised." Such broadening of the terms creates several issues.

First, it reduces the number of plaintiffs who constitute a "non-revised plaintiff," which means it reduces the number of plaintiffs who may elect to dismiss their case and avoid the burdens of litigation. The benefit of allowing non-revised plaintiffs and Defendants to avoid incurring litigation expenses will certainly be decreased.

Second, it impacts the resolution of this multi-district proceeding by deeming a large number of plaintiffs “revised,” which extends the litigation far into the future and limits the Court’s ability to manage this litigation to an end.

Third, such a broadening of the definition significantly increases the number of individuals who may ultimately be entitled to re-file their claim.

The K&S Plaintiffs offer no justification for this change, saying only that Defendants’ definition of Revision Surgery is “overly restrictive and unfairly prejudicial.” Pls.’ Mem. [Doc. No. 5431] at 2. However, it is plain that this change will negatively impact the proposed election procedure.

Expansion of the definition of Revision Surgery to procedures using local anesthetic encompasses very small exposures/erosions that are trimmed in the doctor’s office. As noted in FDA’s *Considerations about Surgical Mesh for SUI*, “Erosion of mesh slings through the vagina is the most commonly reported mesh-specific complication from SUI surgeries with mesh. The average reported rate of mesh erosion at one year following SUI surgery with mesh is approximately 2 percent.” Ex. 1, 2013 Considerations about Surgical Mesh for SUI, at 1. Yet such mesh erosions can sometimes be treated successfully in “an office procedure where the exposed piece of mesh is cut.” *Id.* Such trimming of mesh in a physician’s office is conducted using local anesthesia. Even plaintiffs’ expert, Dr. Rosenzweig, acknowledges that half of mesh erosions require no surgical intervention. Ex. 2, Rosenzweig (2/4/16) Dep. (*McGee v. Ethicon, Inc.*, No. 003483, Pa. Court Common Pleas) at 133:17-20. To include such in-office procedures as revision surgeries greatly expands the field of qualifying procedures well beyond a manageable number.

Defendants' proposed Order already encompasses some non-surgery plaintiffs by including any plaintiff who has had more than one (1) in-office revision of the mesh and who also had concomitant treatments of trigger point injections, vaginal physical therapy or utilization of vaginal Valium. Therefore, plaintiffs whose treatment does not extend to an operating room may be considered Revised Plaintiffs under certain defined circumstances.

Finally, Ethicon notes that this election procedure is purely voluntary on plaintiffs' part. If any of the K&S Plaintiffs feels that she has a serious injury even though hers does not qualify as a revision case, then she may elect not to participate. The K&S Plaintiffs have provided no reason that these plaintiffs' concerns should disqualify large numbers of plaintiffs from participating in the election procedure, particularly where there is no prejudice shown. The K&S Plaintiffs have offered no proof that the definition provided by Defendants is "overly restrictive" at all except for their say so. They have provided no logical basis for the extension of "Revision Surgery" to minor procedures using local anesthesia, and their proposed amendment should be denied.

B. The exclusion of surgeries by physicians retained or funded by plaintiff lawyers or funding companies from the definition of "Revision Surgeries" is material to the proposed Order and will not prejudice plaintiffs.

The K&S Plaintiffs suggest that the following limitation on the definition of Revision Surgery should be removed:

A surgery performed after the date of the dismissal of the pending action by a physician retained or funded by a plaintiff's lawyer to perform the surgery or by a physician retained or funded by any litigation funding company to perform the surgery shall not constitute an acceptable "Revision Surgery." A surgery funded after the date of dismissal of the pending action where the litigation funding company has a relationship with the surgeon performing the surgery or the facility (or any related entity) shall not constitute an acceptable "Revision Surgery."

This limitation is crucial. This Court is familiar with the litigation and surgical funding schemes that have been uncovered in mesh litigation, as detailed in the discovery practice in the AMS and Boston Scientific MDLs. *See, e.g., In re Am. Med. Sys.*, No. 2:12-md-02325, Doc. No. 2355, at 9 (S.D. W. Va. May 31, 2016), and related motions and briefing [Doc. Nos. 2259, 2262 and 2298]. The scenario that has come to light in the Ethicon MDL is not different: A woman receives a “cold” call from a stranger who advises her that the pelvic mesh device she had implanted needs to be removed and helpfully offers to set up the surgery and arrange for her travel at no up-front cost to her – all without her ever having met the surgeon who is scheduled to conduct the explant surgery. *See Phillips v. Ethicon, Inc.*, No. 2:15-cv-03766, Defendants’ Memorandum in Support of Motion for Summary Judgment [Doc. No. 35] at Undisputed Facts (none of which were disputed by Plaintiffs in their Response [Doc. No. 39]). Without the exclusion of such surgeries from the proposed Order, there is a financial incentive to continue the scheme into perpetuity. Such a method of increasing revision surgeries and expenses should be discouraged by this and every court.

Removing this limitation on the definition of a qualifying Revision Surgery creates the real risk that unethical players will target unsuspecting recipients of mesh used to correct their urinary symptoms. Surgery funding schemes may seriously harm the women who have fallen prey to them, potentially subjecting them to unnecessary surgery, eliminating the benefit that mesh provided, and exposing them to exorbitant fees and expenses.

In 2014, the American Urogynecologic Society sent a survey to its members concerning this type of activity, and found that of 202 responses, 92% of physicians indicated that their patients had been contacted by an external source encouraging them to participate in a medical device lawsuit, and the caller knew the patient’s name and procedure-specific information. *See*

Ex. 3. It has also been uncovered that in many of these instances, these sources encouraged women to have their mesh removed. An example of one such communication is attached as Exhibit 4. Recognizing the importance of the issue, Judge Eifert has permitted discovery about “the sources that gave the plaintiffs advice regarding whether to undergo corrective surgeries, as well as information related to the funding of the corrective surgeries” when presented with these allegations. *In re Am. Med. Sys.*, No. 2:12-md-02325, Doc. 2355, at 9 (S.D. W. Va. May 31, 2016); *cf.*, *e.g.*, *Prospect Funding Holdings, LLC v. Saulter et al.*, No. 16-L-3838, 2018 IL App. (1st) 171277 (Ill. App. Mar. 13, 2018) (finding litigation funding contract unenforceable under state law rule prohibiting contracts for champerty); *WFIC, LLC v. Labarre et al.*, 2016 WL 4769436 (Pa. Sup. Ct. Sept. 13, 2016) (finding agreement between litigation funding investors and attorney champertous and invalid).

Notably, such “funded” surgery sometimes occurs in situations where treating physicians who have seen the patient for years have not recommended removal surgery, but patients are encouraged to do so by unknown callers. *See Phillips v. Ethicon, Inc.*, No. 2:15-cv-03766, Defendants’ Motion for Summary Judgment [Doc. No. 35] at Undisputed Facts (none of which were disputed by Plaintiffs in their Response [Doc. No. 39]).

The troubling problems associated with such schemes – legal, ethical, and medical – cannot be overstated. The K&S Plaintiffs’ only rationale for excluding this language is that it is “overly restrictive and unfairly prejudicial.” Pls.’ Mem. [Doc. No. 5431] at 2. It is not. The prejudice actually occurs when a woman is encouraged to participate in this scheme. Excluding the limited scenario of funded surgeries from the Order will remove the incentive for “cold calls” such as those encountered by the patients described above and may help protect unwitting plaintiffs, but will by no means unreasonably restrict access to necessary healthcare.

C. Defendants do not oppose Plaintiffs' addition of a Defense Fact Sheet requirement.

Ethicon does not object to the K&S Plaintiffs' request for a Defendant Fact Sheet requirement, but Ethicon requests sixty (60) days to provide a Defendant Fact Sheet, instead of the thirty days proposed by the K&S Plaintiffs. This timing is equitable, particularly given that plaintiffs are provided 90 days to provide their post-election documentation.

CONCLUSION

The K&S Plaintiffs have not provided a sound reason for the changes they propose, and their proffered amendments should be denied, with the limited exception of the Defense Fact Sheet requirement.

Respectfully submitted,

/s/ William M. Gage

William M. Gage (MS Bar #8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ Susan M. Robinson

Susan M. Robinson (W. Va. Bar #5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

Counsel for Defendants
Ethicon, Inc. and Johnson & Johnson

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
William M. Gage